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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,792	09/15/2003	Robert E. Fischell	JOH2748P0043US	9518
32116	7590	01/12/2005	EXAMINER	
WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661			SWEET, THOMAS	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,792	Applicant(s) FISCHELL ET AL.	
	Examiner Thomas J Sweet	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 36-56 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/15/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 09/15/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. The foreign patent JP 6-41745 and papers dealing with the civil trial were not obtainable from the parent cases and have not been considered. US 5679278 was not considered since the inventor's name does not correspond to the name listed. All redundant entries have been crossed out.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the stent in the first pre-deployment diameter showing all the details of claims 36-56 such as but not limited to a "circumferentially extending generally U-shaped turn back" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

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be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 43 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for turn back portions, does not reasonably provide enablement for turn back portions located entirely within a valley. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There is no such structural relationship disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. It is unclear how in the limited circumstance of having only two rings and only one connector that a multiplicity of perimeter cells can be defined (i.e. only one cell is defined in that situation).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 51-56 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. It is impossible to have a multiplicity of perimeter cells defined in the limited circumstance of having only two rings and only one connector that (i.e. only one cell is defined in that situation).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

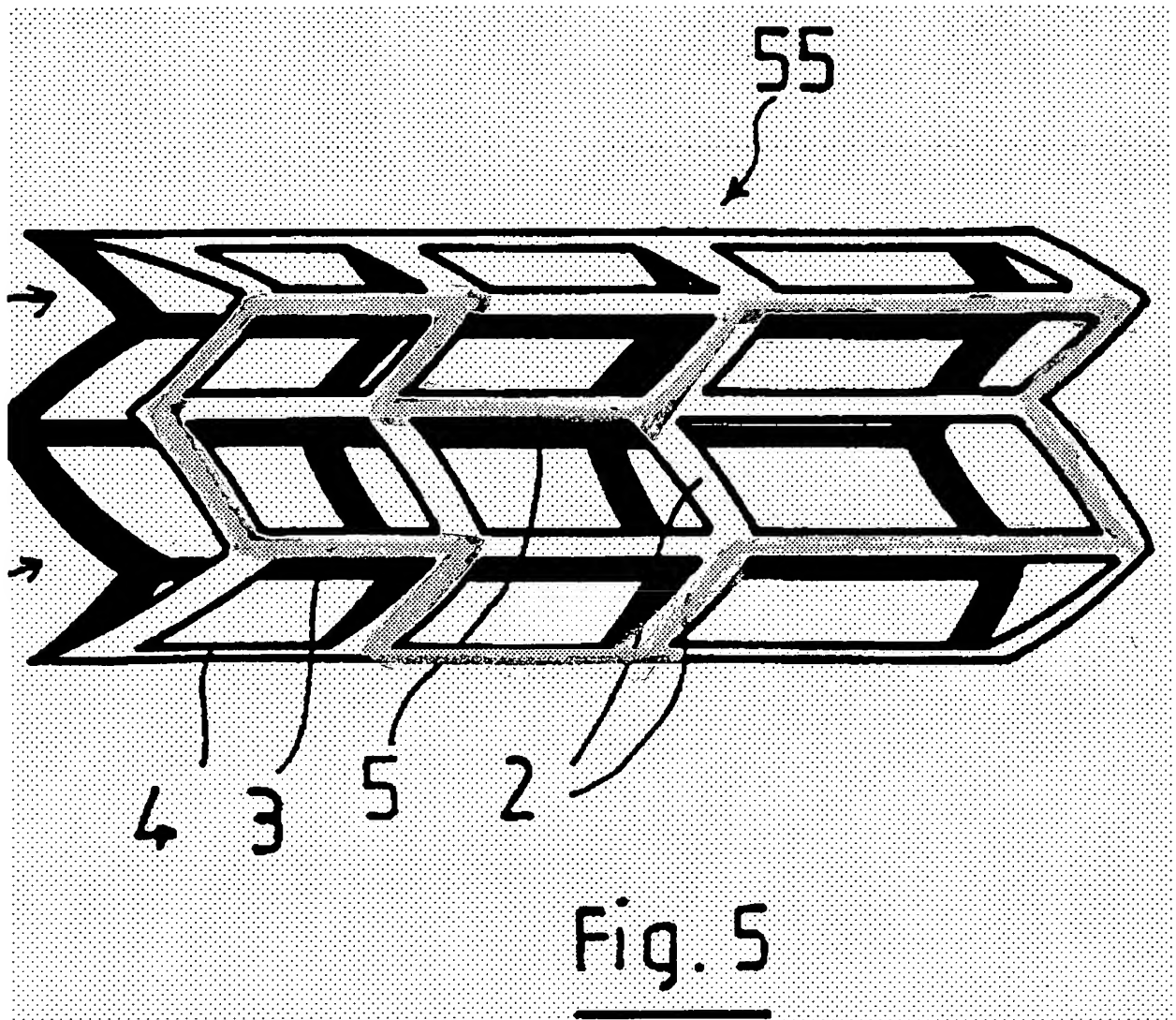
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Sgro (US 5496365). Sgro discloses a generally cylindrical stent (e.g. fig. 5) for delivery to a coronary artery (intended use language, the stent is capable of being used in this way), said stent having a

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first pre-deployment diameter and a second deployed diameter (inherent), said stent being cut from a preexisting metal tube and having a longitudinal axis (intended use language, the stent is capable of being made in this way), said stent having sufficient flexibility (inherent) to permit percutaneous delivery to a curved coronary artery (intended use language, the stent is capable of being used in this way); said stent in its first diameter comprising: a multiplicity of closed perimeter cells, each of said cells including at least one generally U-shaped turn back portion (any cell bounded by at least two #2 members and at least two #3 members has a U-shaped turn back portion, i.e. members #2 to #3 to #2) having a first end point and a second end point wherein a line drawn (the other #3 member) from the first end point to the second end point is generally parallel to the longitudinal axis of the stent.

With regard to claims 47, 48 and 50-54, cells can be bounded as shown below reading on these claims since in the broadest reasonable interpretation of the term cell does not require that it be open.



With regard to claims 55-56, cells can be bounded and include connectors as shown below reading on these claims since in the broadest reasonable interpretation of the term cell does not require that it be open.



Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-42 and 44-56 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6547817 in view of claim 22 of U.S. Patent No. 5643312. Claim 9 of U.S. Patent No. 6547817 includes a generally cylindrical stent for delivery to a coronary artery, said stent having a first pre-deployment diameter and a second deployed diameter, said stent being cut from a pre-existing metal tube and having a circumference and a longitudinal axis, said stent having sufficient flexibility to permit

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percutaneous delivery to a curved coronary artery; said stent in its first diameter comprising: at least two longitudinally spaced apart circumferential rings, each of said circumferential rings defining a portion of the circumference of the stent, each of said circumferential rings having at least two peak segments and at least two valley segments', and at least one connector having a first end portion and a second end portion, said first end portion being fixedly connected to a peak segment of a first of said circumferential rings and said second end portion being fixedly connected to a valley segment of a circumferential ring adjacent to said first circumferential ring, , said connector having at least one circumferentially extending generally U-shaped turn back portion between its first and second end portions that can expand or contract in length, as measured by the straight line distance between its first and second end portions, while being passed through a curved coronary artery. However, claim 9 of 6547817 does not include at least one of said first and second end portions of said connector including a straight segment that is substantially parallel to the longitudinal axis of the stent. Claim 22 of 5643312 includes another connector in which at least one of said first and second end portions of said connector including a straight segment that is substantially parallel to the longitudinal axis of the stent combined with a generally U-shaped turn back portion (sine wave) as a connector with in the art of stents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the connector as taught in claim 22 of 5643312 on the stent of claim 9 of 6547817, because it would amount to mere substitution of one functionally equivalent connector for another with in the art of stents.

With regard to claims 45-50, these claims are met in the embodiment including plural connectors which is within the scope by the invention as modified above.

With regard to claims 51-56, in as much as the present invention meets these claims so does the modified invention, additionally, these claims are met in the embodiment including plural connectors which is within the scope by the invention as modified above.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Palmaz (US 5,382,261) and Fischell et al (US 6,716,240, 5,879,370 and 6,086,604)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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